DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 13,2014

Bard Access Systems, Incorporated
Bryan Stone
Regulatory Affairs Specialist
605 North 5600 West
Salt Lake City, UT 84116

RE: K142267
Sherlock 3CG® Tip Positioning System (TPS) Stylet
Regulation Number: 21 CFR 880.5970
Regulation Name: Accessory to Percutaneous, Implanted Long-Term Intravascular Catheter
Regulatory Class: Class II
Product Code: LJS
Dated: August 14, 2014
Received: August 15, 2014

Dear Mr. Stone:

This letter corrects our substantially equivalent letter of October 17, 2014.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

BARD
ACCESS SYSTEMS

K142267

Indications for Use

510(k) Number (if known): _____

Device Name: Sherlock 3CG® Tip Positioning System (TPS) Stylet

Indications for Use:

Sherlock 3CG® Tip Positioning System Stylet

Catheter stylets provide internal reinforcement to aid in catheter placement. When used with the Sherlock 3CG® Tip Confirmation System (TCS), the Sherlock 3CG® TPS Stylet also provides the placer rapid feedback on catheter tip location and orientation through the use of passive magnets and cardiac electrical signal detection.

Prescription Use ✓ . AND/OR Over-The-Counter Use _____
(Part 21 CFR §801 Subpart D) (21 CFR §801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

BARD
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510(k) Summary
21 CFR 807.92(a)

General Provisions	Submitter Name: Address: Contact Person: Telephone Number: Fax Number: Date of Preparation:	Bard Access Systems, Inc. 605 North 5600 West Salt Lake City, UT 84116 Bryan Stone Regulatory Affairs Specialist (801) 522-5876 (801) 522-5425 8 August 2014
Subject Device	Trade Name: Common Name: Classification Name: Product Code/ Regulation:	Sherlock 3CG® Tip Positioning System Stylet Peripherally Inserted Central Venous Catheter(PICC) Accessory to Percutaneous, Implanted, Long-Term Intravascular Catheter LJS/21 CFR §880.5970
Predicate Devices	Predicate Trade Name: Classification Name: Premarket Notification: Manufacturer:	Sherlock 3CG® Tip Positioning System Stylet, Sherlock 3CG® Tip Positioning System Sensor Accessory to Percutaneous, Implanted, Long-Term Intravascular Catheter K091324 Bard Access Systems, Inc.
Device Description	Bard Access Systems, Inc.'s Sherlock 3CG® Tip Positioning System (TPS) Stylet is a sterile, single use device 0.49 mm (0.019 in) outer diameter x 78.5 cm, made of specially-formulated materials designed to aid in the placement of specific Bard catheters, as well as any open-ended, non-valved, polyurethane, peripherally inserted central catheters (PICCs) that meet the dimensional specifications of the stylet. The Sherlock 3CG® TPS Stylet is designed to work with catheters containing a minimum lumen diameter of 0.51mm (0.020 in). The stylet provides internal reinforcement to aid in catheter placement. The Sherlock 3CG® TPS Stylet may be used with the Sherlock 3CG® Tip Confirmation System (TCS) to provide catheter tip placement information during the procedure.	

Intended Use	The Sherlock 3CG® TPS Stylet provides real time catheter tip location information through the use of passive magnet and cardiac electrical signal detection.
Indications For Use	Catheter stylets provide internal reinforcement to aid in catheter placement. When used with the Sherlock 3CG® Tip Confirmation System (TCS), the Sherlock 3CG® TPS Stylet also provides the placer rapid feedback on catheter tip location and orientation through the use of passive magnets and cardiac electrical signal detection.
Technological Characteristics	Technological characteristics including design, materials and function of the subject Sherlock 3CG® TPS Stylet are identical with respect to those of the predicate Sherlock 3CG® TPS Stylet. The subject device may now be used with specific Bard catheters as well as any open-ended, non-valved, polyurethane peripherally inserted central catheter that meets the dimensional specifications of the stylet (0.020 in minimum lumen diameter).

Safety & Performance Tests	Verification and validation tests have been performed in accordance with Design Controls as per 21 CFR §820.30. The following guidance documents and standards in conjunction with in-house protocols were used to determine appropriate methods for evaluating the performance of the device: • *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, March 16, 1995* • *BS/EN/ISO 10555-1: 1997, Sterile, single-use intravascular catheters, Part 1. General Requirements /ISO 10555-1:2004 Amendment* • *BS/EN/ISO 10555-3:1997, Sterile, single-use intravascular catheters, Part 3. Central venous catheters* • *ISO 594-2: 1998, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment— Part 2: Lock Fittings* • *AAMI/ANSI/ISO 11135-1:2007 Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices - First Edition* • *AAMI/ANSI/ISO 10993-1:2009, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing, and the FDA Modified ISO 10993 Test Profile* The subject devices met all predetermined acceptance criteria derived from the above listed references and demonstrated substantially equivalent performance as compared to the cited predicate devices. Risk management, including a failure modes and effects analysis (FMEA), of the subject device was conducted in accordance with ISO 14971:2012, *Medical Devices – Risk Management for Medical Devices.*
Summary of Substantial Equivalence	Based on the intended use, technological characteristics, and safety and performance testing, the subject Sherlock 3CG® TPS Stylet met the requirements that are considered sufficient for its intended use and is as safe and as effective as predicate devices cited.